No. 2022-2217

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

UNITED THERAPEUTICS CORPORATION,
Plaintiff-Appellee,

v.

LIQUIDIA TECHNOLOGIES INC.,
Defendant-Appellant,

On Appeal from a Judgment of the United States District Court for the District of Delaware, No. 20-cv-755 (Andrews, J.)

UNITED THERAPEUTICS' OPPOSITION TO LIQUIDIA'S MOTION TO EXPEDITE BRIEFING AND ORAL ARGUMENT

The Court should deny Liquidia's request to drastically shorten United Therapeutics' (UT's) briefing deadlines and to expedite the oral argument in this appeal (and two other appeals that have been designated as companion cases). Liquidia has failed to establish any reason—let alone good cause—for that extraordinary relief. The harm it asserts is one that all losing Hatch-Waxman defendants face: an order under 35 U.S.C. §271(e)(4)(A) setting the earliest date on which the FDA may approve Liquidia's proposed product. This routine scenario does not

justify relief that is "not routinely granted." Fed. Cir. R. 27, Practice Note.

Liquidia asserts that this case nevertheless warrants expedited consideration, but the central premises of its argument are flawed—if not misleading. On Liquidia's telling, the PTAB has finally invalidated UT's '793 Patent, and the district court's decision finding that patent valid and infringed conflicts with both precedent and the PTAB's decision. None of that is correct.

First, the PTAB's final written decision will not take effect—and the Patent Office will not cancel any claims of the '793 Patent—unless and until (1) the PTAB denies UT's pending request for rehearing and (2) any future appeal from that IPR decision "has terminated" in Liquidia's favor. 35 U.S.C. §318(b). Second, the one decision that Liquidia cites for the proposition that a not-yet-final invalidity ruling in the PTAB compels a finding of noninfringement in district court says no such thing. On the contrary, that case makes clear that validity and infringement are two entirely separate inquiries. Third, there is no "conflict" between the district court and PTAB decisions because each considered entirely different invalidity arguments—a consequence of Liquidia's decision to

abandon its obviousness arguments midway through the district-court trial and pursue only enablement and written-description challenges there. In other words, the issue that Liquidia's motion focuses on, the obviousness of the '793 Patent, will not arise in the three appeals that are currently pending in this Court. Obviousness will come up, if at all, only in a potential future appeal from the PTAB's final written decision on the '793 Patent—which no party can even bring until the PTAB acts on UT's rehearing request.

Moreover, the prejudicial impact of Liquidia's requested schedule on UT is particularly inappropriate because Liquidia's request flows from its own strategic decision to pursue an IPR on the '793 Patent and abandon those arguments in the district-court litigation. Liquidia knew when it made that choice, well after the '793 Patent was asserted, that the IPR could not result in cancellation of the '793 Patent until after any appeals from the PTAB's decision. *See, e.g.*, D. Del. Dkt. No. 428, at 1-2; Liquidia Mot. Ex. 3 (Trial Op.) at 36. Liquidia also knew that, if the district court found the '793 Patent valid and infringed, it would have no choice but to order the effective date of final FDA approval of Liquidia's product to be a date "which is not earlier than the date of the expiration"

of that patent. 35 U.S.C. §271(e)(4)(A). UT should not have to prepare its briefs in half-time simply because Liquidia made a strategic choice to pursue an IPR instead of presenting its anticipation and obviousness defenses in district court.

Liquidia is free to self-expedite its own briefs, and UT takes no position on when the Court should schedule oral argument—UT will appear at the Court's convenience. But Liquidia has not come close to justifying the compression of UT's briefing schedule.

BACKGROUND AND PROCEDURAL HISTORY

UT brought this patent-infringement suit because Liquidia plans to market an inhalation powder that will infringe three of UT's patents: the '066, '901, and '793 Patents. Liquidia Mot. at 1; Trial Op. at 1. When seeking FDA approval to market that product, Liquidia certified that UT's patents were invalid and not infringed, triggering this litigation in accordance with the Hatch-Waxman framework. Liquidia Mot. at 1-2; Trial Op. at 2. Liquidia advanced its invalidity and noninfringement arguments in the district court, *see, e.g.*, D. Del. Dkt. No. 365, Ex. 3, and also brought parallel IPRs challenging all three patents, *see* Nos. IPR2020-00769, IPR2020-00770, IPR2021-00406. The PTAB instituted

reviews on the '901 and '793 Patents but declined to institute review of the '066 Patent.

The PTAB concluded that claims 1-5, 8, and 9 of the '901 Patent were obvious, while claims 6-7 were not. Liquidia Mot. Ex. 5 ('901 FWD) at 2. Both parties have appealed the PTAB's final written decision. In district court, following claim construction, UT stipulated to noninfringement of the asserted '901 Patent claims. Liquidia Mot. Ex. 6 (Stipulation). Thus, the '901 Patent does not currently have any effect on Liquidia's ability to market its product.

With respect to the '793 Patent, Liquidia's invalidity defenses in the district court originally included obviousness and anticipation arguments. *See* D. Del. Dkt. No. 365, Ex. 3, at 150-185 (advancing these arguments in final pretrial submissions). But then, on the second day of trial, Liquidia made a strategic choice: it dropped these arguments, leaving them to be litigated *solely* in the parallel IPR proceeding, and limited its district-court invalidity defenses on the '793 Patent to written-description and enablement issues only. *See* Trial Op. at 39-53.

Thereafter, in the '793 Patent IPR, the PTAB concluded that the claims of the '793 Patent are obvious. Liquidia Mot. Ex. 7 ('793 FWD) at

2, 46-47. UT filed requests for rehearing and for review of that decision by the PTAB's Precedential Opinion Panel. *See* No. IPR2021-00406, Papers 79-80. Both requests are still pending. If they are denied, UT intends to appeal the PTAB's decision to this Court.

Meanwhile, in district court, Judge Andrews found after a four-day bench trial that Liquidia will infringe claims 1, 4, 6, 7, and 8 of the '793 Patent, and that Liquidia had not shown that the patent was invalid for lack of enablement or adequate written description. Trial Op. at 53. Because Liquidia had abandoned its obviousness challenges in the district-court litigation, the district court made no findings regarding obviousness. The district court also found that Liquidia had proven that claims 1, 2, 3, 6, and 9 of the '066 patent are invalid; had not proven the invalidity of claim 8; and will not infringe claim 8. *Id.*

The district court subsequently entered final judgment. Consistent with 35 U.S.C. §271(e)(4)(A), the court "ordered that the effective date of any final approval by the FDA of Liquidia's [application for its inhaled powder product] shall be a date which is not earlier than the expiration date of the '793 patent." Liquidia Mot. Ex. 4 (Final Judgment) ¶4. Liquidia appealed the district court's judgment as to the '793 Patent, and

UT cross-appealed the district court's judgment as to the '066 Patent.

ARGUMENT

"[M]otions to expedite proceedings are not routinely granted," Fed. Cir. R. 27, Practice Note. Liquidia asserts that it will be harmed without expedited briefing.[1] But Liquidia has been harmed no more than any other Hatch-Waxman defendant that loses at trial. Liquidia took advantage of the Hatch-Waxman statutory framework to rely on UT's data and thereby secure abbreviated FDA review of its application and pre-approval district court litigation. It cannot turn around and argue that a routine element of that same framework—the §271(e)(4)(A) remedy—justifies extraordinary relief.

Nothing about this case justifies departing from the Court's standard practice or imposing shortened deadlines on UT. Liquidia suggests that, unless the Court indulges Liquidia's request for an expedited schedule, it will be wrongly foreclosed from marketing its

[1] Liquidia also suggests that patients will be harmed without expedited briefing, Liquidia Mot. at 3, but that conclusory assertion ignores the fact that patients already have access to treprostinil drugs, including UT's own dry powder inhalation formulation (Tyvaso DPI). Other drugs include injection products (Remodulin and Liquidia's own generic copy), a liquid formulation for inhalation (Tyvaso), and a tablet formulation (Orenitram).

product. But there is nothing wrong with following the statute that Congress enacted, and Liquidia misrepresents both the effect of the PTAB's '793 Patent final written decision and the differences between that pending case and the ones currently on appeal before the Court. Moreover, Liquidia's manufactured sense of urgency arises from its own actions and strategic choices. Liquidia remains free to self-expedite its own briefs, but the Court should deny Liquidia's motion.

I. The PTAB's final written decision regarding the '793 Patent is irrelevant to this appeal and its briefing schedule.

Liquidia's motion rests on three premises: that the PTAB has *already* invalidated the '793 Patent; that the Supreme Court's decision in *Commil USA, LLC v. Cisco Systems, Inc.*, 575 U.S. 632 (2015), somehow compels the district court to find noninfringement; and that the district court's decision in this case "conflict[s]" with the PTAB's final written decision on the '793 Patent. Liquidia Mot. at 4. Liquidia is wrong on all counts. There is no urgency on these facts.

First, it is false to suggest that the PTAB has *already* invalidated the '793 Patent. *See, e.g.*, Liquidia Mot. at 3 (suggesting that the patent "has been rendered unpatentable"); *id.* at 5 (suggesting that this Court should expedite the appeal "given the PTAB's decision rendering

unpatentable all asserted claims of the '793 patent"). Rehearing is still pending in the PTAB, and even if it were not, the PTAB's final written decision on the '793 Patent is not self-executing. Instead, 35 U.S.C. §318(b) provides that such a decision takes effect only if affirmed on appeal:

> If the Patent Trial and Appeal Board issues a final written decision under subsection (a) *and the time for appeal has expired or any appeal has terminated*, the Director shall issue and publish a certificate canceling any claim of the patent finally determined to be unpatentable, confirming any claim of the patent determined to be patentable, and incorporating in the patent by operation of the certificate any new or amended claim determined to be patentable.

(emphasis added). This plain language makes clear that the claims of the '793 Patent can be cancelled only if and when the Director issues the required certificate—which can happen only after any appeals are over and only if those appeals are resolved in Liquidia's favor. *Cf. Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 645 (Fed. Cir. 2011) (explaining, in applying §318's predecessor, that "a determination of patentability [can] occur only after all appeals have terminated"). Until then, the '793 Patent remains valid.

Second, Liquidia incorrectly argues (Mot. at 5) that the district court's "fail[ure] to properly take into account the PTAB's decision"

conflicts with the Supreme Court's decision in *Commil USA, LLC v. Cisco Systems, Inc.*, 575 U.S. 632 (2015). The very language that Liquidia quotes makes clear why that is wrong. The Supreme Court explained that "if [a] patent is indeed invalid, and shown to be so *under the proper procedures*, there is no liability." 575 U.S. at 644 (emphasis added). As discussed above, the "proper procedures" here include the issuance of an appropriate certificate by the PTO. Liquidia agreed that the PTAB's decision "does not compel [the district court] to enter a decision finding the '793 patent invalid," arguing instead that it makes it impossible to find infringement. D. Del. Dkt. No. 427, at 1. *Commil* itself contradicts Liquidia's argument: "infringement and invalidity are separate matters under patent law." 575 U.S. at 643 ("When infringement is the issue, the validity of the patent is not the question to be confronted."). In other words, as Judge Andrews correctly explained, "[t]he Supreme Court never stated . . . that a PTAB decision invalidating patent claims in an IPR will preclude liability before it becomes final and nonappealable." D. Del. Dkt. No. 433, at 36. Unless and until the PTO Director issues a certificate after all appeals have been exhausted, the patent is valid and remains in force—and an infringer is subject to liability.

Third, it is false to suggest that the district court's decision and the PTAB's decision are "conflicting decision[s] on [the] validity" of the '793 Patent. Liquidia Mot. at 4. The two decisions considered entirely different invalidity challenges. In the IPR proceedings, Liquidia argued that the '793 Patent was invalid as obvious or anticipated over several references. *See supra*, p. 5. In the district-court proceedings, Liquidia abandoned those arguments at trial for its own strategic reasons and ultimately pressed *only* written-description and enablement challenges at trial. *See id.* Thus, those written-description and enablement challenges are the *only* invalidity arguments it can make in this appeal.[2] There is simply no "conflict." Liquidia chose to pursue its anticipation and obviousness arguments in a separate forum on a separate timeline.

For all those reasons, the grounds that Liquidia has offered for expediting these appeals do not withstand scrutiny. In the end, Liquidia

[2] Even when Liquidia sought a partial stay of judgment in the district court permitting it to launch its infringing product immediately, it never argued that it is likely to prevail in appealing the district court's written-description, enablement, or infringement findings. Instead, it has always hinged its argument on the outcome of the PTAB proceedings, which, as noted above, are still pending. Thus, Liquidia has never even attempted to make a showing that the outcome of *this* appeal is likely to permit Liquidia to launch its infringing product.

simply seeks to expedite for the sake of expediting.

II. Liquidia's self-inflicted sense of urgency does not justify expediting UT's briefing schedule.

Even if Liquidia could persuade the Court that there is some need for expedited briefing, the Court should not entertain Liquidia's request because the claimed need resulted from Liquidia's own conduct. As discussed, Liquidia chose to pursue an IPR knowing full well that the PTAB's final written decision would not bind the district court unless and until affirmed on appeal. *See supra*, p. 3. Liquidia chose not to move to stay the district court proceedings when IPR was instituted on the '793 Patent. And it chose to abandon its obviousness arguments as to the '793 Patent in the district court, even though it knew that if the court found the '793 Patent infringed and not invalid, UT would be entitled to an order barring final FDA approval of Liquidia's product under 35 U.S.C. §271(e)(4)(A). *See supra*, pp. 3-5.

This Court should not order expedited proceedings—a form of relief that is "not routinely granted," Fed. Cir. R. 27, Practice Note—solely to save Liquidia from the statutory consequences of its own strategic decisions to secure a more favorable burden of persuasion on its obviousness challenges to the '793 Patent. Liquidia is free to file its own

briefs early. But the fact that Liquidia is now unhappy with the consequences of its litigation strategy is no reason to burden UT by artificially compressing UT's briefing deadlines for three (soon-to-be-four) appeals,[3] two of which address a completely different patent.

III. Liquidia's proposed schedule is prejudicial to UT.

At the very least, the Court certainly should not adopt the lopsided briefing deadlines that Liquidia has proposed. Liquidia has had the district court's decision in hand since August 31. Yet it proposes to have its own opening brief due 45 days later, on October 14, while giving UT only 20 days for its principal and response brief. And it would give UT only 12 days for its cross-appeal reply, of which the first four are Thanksgiving and the holiday weekend.

Liquidia also insists that this appeal must remain on the same schedule as the '901 IPR appeals—seeking to obscure the fact that it has absolutely no basis for expediting the '901 IPR appeals, which concern a patent that is not currently affecting Liquidia's ability to market its product. Even if the Court were to deem expedition appropriate in this

[3] UT noticed its cross-appeal from the district court's judgment after Liquidia filed its motion; that cross-appeal will presumably be consolidated with this appeal.

appeal, it certainly should not expedite the '901 IPR appeals just because the Court linked them as companion cases. The Court could simply decouple the appeals and keep the '901 IPR appeals on a normal schedule. It certainly should not force UT to file its opening brief in those appeals barely two weeks from now, and only about three weeks after Liquidia broached the subject of expedition.

CONCLUSION

The Court should deny Liquidia's motion.

October 4, 2022

Respectfully submitted.

/s/ *Jaime A. Santos*

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number	22-2217
Short Case Caption	United Therapeutics Corporation v. Liquidia Technologies, Inc.
Filing Party/Entity	United Therapeutics Corporation

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 10/04/2022

Signature: /s/ Jaime A. Santos

Name: Jaime A. Santos

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
United Therapeutics Corp.		BlackRock Inc.

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☐ None/Not Applicable ☐ Additional pages attached

CAFC Nos. 22-2133, -2174, United Therapeutics Corporation v. Liquidia Technologies, Inc.	PTAB No. IPR2021-00406, Liquidia Technologies, Inc. v. United Therapeutics Corporation	

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

CERTIFICATE OF COMPLIANCE

This response complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2)(A) because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 27(d), it contains 2,710 words.

This response complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared using Microsoft Word for Office 365 in 14-point Century Schoolbook, a proportionally spaced typeface.

CERTIFICATE OF SERVICE

I hereby certify that on October 4, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit using the Court's CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the CM/ECF system.

/s/ *Jaime A. Santos*
Jaime A. Santos